STATE OF MINNESOTA OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE BOARD OF PHARMACY

In the Matter of the Proposed Rules Relating to Pharmacy Regulations,	REPORT OF THE CHIEF ADMINISTRATIVE LAW JUDGE
Minnesota Rules, Chapter 6800	

The above-entitled matter came on for review by the Chief Administrative Law Judge pursuant to the provisions of Minnesota Rules, part 1400.2240, subpart 4. Based upon a review of the record in this proceeding, the Chief Administrative Law Judge hereby approves the Report of the Administrative Law Judge, dated January 11, 2007, in all respects.

In order to correct the defect enumerated by the Administrative Law Judge in the attached Report, the agency shall either take the action recommended by the Administrative Law Judge, make different changes to the rule to address the defect noted, or submit the rule to the Legislative Coordinating Commission and the House of Representatives and Senate policy committees with primary jurisdiction over state governmental operations, for review under Minnesota Statutes, section 14.15, subdivision 4.

If the agency chooses to take the action recommended by the Administrative Law Judge, or if the agency chooses to make other changes to correct the defect, it shall submit to the Chief Administrative Law Judge a copy of the rules as originally published in the State Register, the agency's order adopting the rules, and the rule showing the agency's changes. The Chief Administrative Law Judge will then make a determination as to whether the defect has been corrected and whether the modifications to the rules make them substantially different than originally proposed.

Dated this 18th day of January, 2007.

_/s/ Raymond R. Krause RAYMOND R. KRAUSE Chief Administrative Law Judge

STATE OF MINNESOTA OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE BOARD OF PHARMACY

In the Matter of the Proposed Rules Relating to Pharmacy Regulations, Minnesota Rules, Chapter 6800.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge Kathleen D. Sheehy conducted a hearing concerning the above rules beginning at 9:00 a.m. on November 14, 2006, in the University Room, University Park Plaza, 2829 University Avenue SE, Minneapolis, Minnesota. The hearing continued until all interested persons, groups and associations had an opportunity to be heard concerning the proposed rules.

The hearing and this Report are part of a rulemaking process governed by the Minnesota Administrative Procedure Act.¹ The legislature has designed the rulemaking process to ensure that state agencies have met all of the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable, that they are within the agency's statutory authority, and that any modifications that the agency may have made after the proposed rules were initially published are not impermissible substantial changes.

The rulemaking process includes a hearing when a sufficient number of persons request that a hearing be held. The hearing is intended to allow the agency and the Administrative Law Judge reviewing the proposed rules to hear public comment regarding the impact of the proposed rules and what changes might be appropriate. The Administrative Law Judge is employed by the Office of Administrative Hearings, an agency independent of the Board of Pharmacy (Board).

The members of the Board's hearing panel were Cody Wiberg, Executive Director; and Board members Vern Kassekert, Gary Schneider, Kay Hanson, and Carleton Crawford. Forty-five members of the public signed the hearing register and twenty-three members of the public spoke at the hearing.

The Board of Pharmacy received a substantial number of written comments on the proposed rules before the hearing. After the hearing, the record remained open for five business days, until November 21, 2006, to allow interested persons and the Board an opportunity to submit written comments. Following the initial comment period, the record remained open for an additional five days to allow interested persons and the Board the opportunity to file a written response to the comments submitted. The Board's response proposing a number of changes to the proposed rules (dated November 22, 2006) was received on November 28, 2006. To allow the public time to

¹ Minn. Stat. §§ 14.131 through 14.20.

respond to the Board's additional proposed amendments, the Administrative Law Judge extended the time for comment to December 8, 2006. The OAH hearing record closed on December 8, 2006. On December 21, 2006, the Administrative Law Judge received additional information regarding the Board's compliance with Minn. Stat. §§ 14.127 and 14.131. All of the comments received were read and considered.

SUMMARY OF CONCLUSIONS

The Board has established that it has the statutory authority to adopt the proposed rules and that the rules are necessary and reasonable, with one exception at Finding 115.

Based upon all the testimony, exhibits and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Nature of the Proposed Rules

- This rulemaking proceeding involves revising the rules governing pharmacy regulations. Specifically, the proposed rules relate to definitions, license categories, pharmacy satellites, patient access to pharmacists, closing a pharmacy, required reference books and equipment, applications for licensure, reciprocal licensure, drug manufacturer or wholesaler licensure, pharmaceutical waste, vending machines, return of drugs and devices, prescription numbers, electronic prescriptions, compounding and dispensing, transferring of prescriptions between pharmacies, prepackaging and labeling, pharmacy compounding practices, beyond-use dates, prescription labeling, labeling of out-patient intravenous admixture drugs, electronic data processing, Schedule III and V controlled substances, registration of controlled substance substance researchers. controlled samples, prescription communication, hospital pharmacist-in-charge, patient care, pharmaceutical service policies, policy and procedures manuals, physical requirements, service and filing of papers, variances, registration of medical gas retailers, and continuing pharmaceutical education.
- 2. The Board maintains that the proposed rules are needed because the professional practice of pharmacy is continuously evolving, requiring the Board to periodically revise its rules to address changes in practice.² Furthermore, actions of the United States Congress, the Food and Drug Administration, the Drug Enforcement Administration and other federal agencies often require changes in the Minnesota Rules regulating the practice of pharmacy.
- 3. In developing the proposed rules, the Board sought input from two ad hoc committees of practicing pharmacists, one focusing on institutional practice and one on community practice. The committees included representatives of the Minnesota Pharmacists Association, the Minnesota Society of Health System Pharmacists, chain pharmacy management, long-term care pharmacies, and independent pharmacies.

² Exhibit 4, page 2.

According to the Board, these groups represent virtually all facets of the pharmacy profession that would be affected by these proposed rule changes.³

4. The most significant proposed amendments to the rules deal with central service pharmacies, centralized prescription processing and filling, patient access to the pharmacist, the types of facilities that may return unused drugs to the dispensing pharmacy for redispensation, notice requirements, and prescription labeling requirements.

Procedural Requirements of Chapter 14

- 5. On January 10, 2005, the Board published a Request for Comments on Possible Amendments to Rules Governing Pharmacy Practice. The Request indicated that the Board was considering amending the rules addressing definitions, counseling for all patients, reference book requirements, pharmaceutical compounding, licensure by examination, continuing education requirements, returns of medications, electronic prescriptions, central fill, accountability, tablet description, record storage, quality assurance, controlled substance rescheduling, controlled substance researchers, and variances. The Request for Comments was published at 29 State Register 834-835.⁴
- 6. The Board members met on January 11, 2006, a quorum was present, and the Board adopted a Certificate of the Board of Pharmacy Authorizing Resolution for the proposed rules.⁵
- 7. By letter dated September 7, 2006, the Board requested that the Office of Administrative Hearings schedule a hearing and assign an Administrative Law Judge. The Board also filed a proposed Dual Notice, a copy of the proposed rules and a draft of the Statement of Need and Reasonableness (SONAR).
- 8. In a letter dated September 14, 2006, Administrative Law Judge Kathleen Sheehy approved the Board's Dual Notice and Additional Notice Plan.
- 9. On September 19, 2006, the Board mailed the Dual Notice of Hearing to all persons and associations who had registered their names with the agency for the purpose of receiving such notice and to all persons identified in the additional notice plan. The Dual Notice stated that a copy of the proposed rules was attached to the notice.⁶
- 10. On September 19, 2006, the Board sent a copy of the Dual Notice and Statement of Need and Reasonableness by inter-office mail to the legislators specified in Minn. Stat. § 14.116.⁷
- 11. On September 19, 2006, the Board mailed a copy of the Statement of Need and Reasonableness to the Legislative Reference Library.⁸

³ Ex. 4, p. 22.

⁴ Ex. 1; Minn. Stat. § 14.101.

⁵ Ex. 2.

⁶ Ex. 6.

⁷ Ex. 11.

⁸ Ex. 5.

- 12. On October 2, 2006, the proposed rule and the Dual Notice of Hearing were published at 31 State Register 429.9
- 13. On the day of the hearing the following documents were placed in the record:
 - The Request for Comments published January 10, 2005 at 29 SR 834 (Ex. 1);
 - Certificate of the Board of Pharmacy Authorizing Resolution (Ex. 2);
 - A copy of the proposed rule with Revisor's approval dated August 31, 2006 (Ex. 3);
 - A copy of the Statement of Need and Reasonableness (SONAR) (Ex. 4);
 - A copy of the cover letter sending the SONAR to the Legislative Reference Library (Ex. 5);
 - The Dual Notice of Hearing as published in the State Register at 31 SR 429 (Ex. 6);
 - Certificate of Mailing the Dual Notice of Hearing to the Rulemaking Mailing List dated September 19, 2006 (Ex. 7);
 - Certificate of Accuracy of the Mailing List dated September 18, 2006 (Ex. 8);
 - Certificate of Giving Additional Notice Pursuant to Additional Notice Plan dated September 19, 2006 (Ex. 9);
 - Copies of letters and emails requesting a hearing and written comments on the proposed rules received by the Board before the hearing (Exs. 10-A through 10-TTTT);
 - Certificate of Sending the Notice to Legislators dated September 19, 2006 (Ex. 11);
 - Board's Response to Comments Received During the October 2 November 1, 2006 Comment Period (Ex. 12);
 - Written comments from the public received at and after the hearing (Exs. 13-19; 21-46); and
 - Sample of a "unit dose package" (Ex. 20).

Additional Notice

14. Minnesota Statutes §§ 14.131 and 14.23, require that the SONAR contain a description of the Board's efforts to provide additional notice to persons who may be affected by the proposed rules. The Board submitted an additional notice plan to the Office of Administrative Hearings, which reviewed and approved it by letter dated September 14, 2006. In addition to notifying those persons on the Department's

⁹ Ex. 6.

rulemaking list, the Board represented that it would also provide notice to the following groups and individuals:

- pharmacists;
- pharmacist interns; and
- pharmacy technicians.

Statutory Authorization

- 15. The Board is authorized pursuant to Minn. Stat. § 151.06, subd. 1(c) "to make and publish uniform rules not inconsistent herewith for carrying out and enforcing the provisions of this chapter. The board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists."
- 16. In addition, the Board is "authorized to regulate and define additional substances which contain quantities of a substance possessing abuse potential" in accordance with the schedule described in Minn. Stat. § 152.02, subd. 7.
- 17. The Administrative Law Judge finds that the Department has the statutory authority to adopt the proposed rules.

Regulatory Analysis in the SONAR

- 18. The Administrative Procedure Act requires an agency adopting rules to consider seven factors in its Statement of Need and Reasonableness. The first factor requires:
 - (1) A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

The Board lists the following as the classes of persons who will be primarily affected by the rules:¹⁰

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pharmacists;
pharmacy owners;
pharmacy technicians;
pharmacist interns; and
support staff.
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¹⁰ SONAR at 36.

The Board states that pharmacy owners will bear most of the costs associated with the rule changes. The other affected parties may experience changes in the policies and procedures used in their work settings. According to the Board, some of the changes might slightly increase the workload of the affected parties, but other changes may result in increased efficiencies.¹¹

The Board states that the public will benefit from many of the proposed changes because the changes should result in the safer provision of pharmacy services. The public will most likely benefit from increased patient counseling and drug use review and better prescription labeling.¹²

(2) The probable costs to the Agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The Board asserts that the only cost it might incur is a small one related to system changes needed to establish a new category of pharmacy licensure. In the Board's opinion, none of the other proposals is likely to result in any costs to the Board or significant costs to other state agencies. It is possible that the pharmacies operated by state agencies, such as the Department of Human Services, might have some minor costs related to upgrading computers and other equipment. Finally, the Board does not anticipate that the proposed changes will have any effect on state revenues.¹³

(3) The determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

The Board states that many of the proposed rule changes simply reflect evolving standards for pharmacy practice recently developed by the United States Pharmacopoeia (USP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The Board argues that while there may be less costly and intrusive methods of dealing with compounding, disposal of hazardous pharmaceutical waste, communication of prescription orders, medication reconciliation, continuous quality improvement and other issues, those less costly and intrusive measures would not be in compliance with the standards set by the state and national organizations regulating the practice of pharmacy. In addition, other less costly and intrusive measures would not adequately achieve the purpose of these proposed rules, which is to further improve the health, safety and welfare of the public.

Furthermore, the Board asserts that adoption of these newer standards may decrease medication errors and drug-related morbidity and mortality. That, in turn,

¹² SONAR at 36.

¹¹ SONAR at 36.

¹³ SONAR at 36.

¹⁴ SONAR at 36. The Board's current rules also reflect standards of pharmacy practice set forth by the National Coordinating Council for Medication Error Reporting & Prevention, the Drug Enforcement Administration (DEA), and the Minnesota Pollution Control Agency. *Id.*¹⁵ SONAR at 37.

would decrease costs for patients, insurers, employers, federal, state and local governments and society as a whole.¹⁶

(4) A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

The Board states that it employed an open process when developing these proposed rule changes. It convened two committees with members drawn from many areas of the pharmacy profession in Minnesota, including representatives of the two major professional associations of pharmacists in Minnesota. The Board considered, and ultimately proposed, many of the alternatives suggested by the advisory committee members or by individuals who testified at the Board meeting at which the Board formally adopted the proposed rules.¹⁷

(5) The probable costs of complying with the proposed rules.

The Board estimates that pharmacies and other healthcare facilities may incur costs in the following areas when implementing the new rules:

- The proposed rules regarding non-sterile and sterile compounding facilities, equipments and procedures. While many pharmacies have already voluntarily made the changes required by this part of the rule, it is likely that others will need to invest in additional equipment and, in the case of sterile compounding, may have to remodel their facilities.
- The proposed rules regarding disposal of pharmaceutical waste. Pharmacies may need to contract with a company licensed to accept and dispose of pharmaceutical waste. As an added factor, the Minnesota Pollution Control Agency has recently been levying fines against some pharmacies that have not been following the laws and rules regarding disposal of pharmaceutical waste.
- The proposed rules that require that the label of prescription containers and prepackaged drugs contain a physical description of the drug, including any identification code that may appear on tablets and capsules. Pharmacies that do not already use software that allows for the inclusion of this information on labels may need to change or update their existing software programs.
- The proposed \$100 fee that will be assessed to cover the costs of handling requests for an extension of time to complete the required continuing education requirement for any pharmacist who files for such an extension.
- The proposed rules regarding monitoring temperatures of refrigerators in which drugs are stored. There will probably be a relatively small cost for

¹⁶ SONAR at 37.

¹⁷ SONAR at 37.

the purchase of the monitoring logs or equipment necessary to comply with this rule change.

Many of these proposed changes have been recommended or mandated by the USP, DEA, JCAHO, the Minnesota Pollution Control Agency or other governmental or standard-setting organizations. Therefore, pharmacies would be likely to incur many of these costs even if the Board did not change its rules.¹⁸

(6) the probable costs or consequences of not adopting the proposed rule, including those costs borne by individual categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

The Board suggests that many of the proposed changes will promote safer use of medications and reduce medication errors and drug-related morbidity and mortality. Accordingly, the Board asserts that the failure to adopt these rules may cause patients to experience these types of problems, which would result in increased costs to patients, insurers, employers, federal, state and local governments and society in general. Failure to adopt the rules may also cause pharmacies to have more costly malpractice insurance premiums and legal judgments rendered against them.

(7) An assessment of any differences between the proposed rules and existing federal regulation and a specific analysis of the need for and reasonableness of each difference.

The Board states that the proposed rules regarding scheduling of controlled substances, the handling of pharmaceutical waste, and compounding sterile and non-sterile substances bring the state rules into compliance with federal law, rules, and standards. The proposed rules should also encourage greater compliance with the patient counseling and drug utilization review (DUR) provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90).²⁰

Performance Based Rules

- 19. The Administrative Procedure Act²¹ also requires an agency to describe how it has considered and implemented the legislative policy supporting performance based regulatory systems. A performance based rule is one that emphasizes superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.²²
- 20. The Board states that the proposed rules are designed to offer flexibility in meeting the requirements in a number of different areas. As to patient counseling and DUR services to patients, the Board has not limited pharmacists in the manner in which such services are provided. Pharmacists have flexibility in using their best professional judgment regarding the provision of counseling services to patients and may utilize their

¹⁹ SONAR at 38.

¹⁸ SONAR at 38.

²⁰ SONAR at 39.

²¹ Minn. Stat. § 14.131.

²² Minn. Stat. § 14.002.

own intrinsic knowledge or rely on any number of computer software programs designed to provide prospective drug use review. Similarly, pharmacists may choose from a variety of vendors when modifying or purchasing software to comply with the proposed changes in labeling.²³

21. The Board argues that the proposed rule changes do not increase the regulatory burden on licensees because they are already required to follow many of the changes that are based on existing state and federal law. Specifically, as to USP 795 and 797 compounding standards, the Board states that it already makes recommendations to pharmacies to help them select the most appropriate and cost-effective solutions for meeting these standards.²⁴

Consultation with the Commissioner of Finance

- 22. Under Minn. Stat. § 14.131, the Agency is also required to "consult with the commissioner of finance to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."
- 23. The Board consulted with its Department of Finance representative Doug Green and predicted that the proposed rules would have no fiscal impact on units of local government. In a memorandum dated November 14, 2006, Mr. Green wrote:
 - I have reviewed the proposed rules and corresponding statements of need and reasonableness (SONAR). Based on my evaluation, the proposed rules may have a fiscal impact on local units of government, although it is not possible to determine what that impact may be at this time. However, the board has adequately considered the impact, both positive and negative, of the proposed rules on local units of government and communicated those potential impacts with all appropriate parties.
- 24. The Board did not forward Mr. Green's memorandum to the Administrative Law Judge until December 21, 2006, in response to questions from the Administrative Law Judge about whether the Board had complied with some procedural requirements of the Administrative Procedure Act (APA). Although this requirement was satisfied before the hearing record closed, it was not forwarded to the Administrative Law Judge until after the record closed. The Administrative Law Judge finds that this was a harmless procedural defect under Minn. Stat. § 14.26, subd. (3)(d)(1).
- 25. The Administrative Law Judge finds that the Board has met the requirements set forth in Minn. Stat. § 14.131 for assessing the impact of the proposed rules, including consideration and implementation of the legislative policy supporting performance-based regulatory systems.

Analysis Under Minn. Stat. § 14.127

26. Effective July 1, 2005, under Minn. Stat. § 14.127, the Board must "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for: (1) any one business that has less than 50 full-

²³ SONAR at 39.

²⁴ SONAR at 39.

time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees."²⁵ The Board must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.²⁶

- The Board has determined that the cost of complying with the proposed rules in the first year after they take effect could exceed \$25,000 for small pharmacies that might have to buy additional equipment or remodel their facilities to come into compliance with USP Chapter 797. These additional costs could total more than \$25,000 in the first year. The Board argues, however, that the rule changes regarding USP 797 are for clarity and do not actually impose a new burden on pharmacies. Under Minn. Stat. § 151.06, subd. 1(3), the Board has both the power and the duty to require that USP standards be used. The Board states that it is aware that complying with USP 797 might be particularly hard on small hospital pharmacies in rural areas, so the Board has been giving pharmacies advice on how to minimize the costs associated with compliance.27
- 28. The Board did not submit the analysis above until December 21, 2006, again at the request of the Administrative Law Judge. The Board was under the impression that this analysis was already covered in the SONAR under its discussion of "the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals," pursuant to Minn. Stat. § 14.131
- The Administrative Law Judge finds that the agency has made the determination required by Minn. Stat. § 14.127. The Board's determination that the cost of compliance with USP Chapter 797 might exceed \$25,000 in the first year after the rule takes effect for small businesses is approved. Minn. Stat. § 14.127 requires a separate analysis specifically directed at the cost of compliance for small businesses and cities. Although the Board has statutory authority to require compliance with USP standards, the Board has not explicitly required compliance with USP Chapter 797 in the past. These are new costs that small businesses and cities may face in the first year after this rule takes effect. The Board has adequately considered these costs, however; it has notified the public concerning what will be required to comply; and it has demonstrated that it will work with small businesses or cities to minimize the costs to achieve compliance.
- The Administrative Law Judge also finds that the agency failed to make this determination before the close of the hearing record, as required by subdivision 2. This constitutes a procedural defect in the rules. It is the determination of the Administrative Law Judge, however, that this delay did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process. Furthermore,

²⁵ Minn. Stat. § 14.127, subd. 1 (2005).

²⁶ Minn. Stat. § 14.127, subd. 2 (2005).

See Email correspondence from the Board dated December 21, 2006. Specifically, the Board stated that it informed small hospital pharmacies that do not deal with large volumes of sterile compounding that they can often comply with USP 797 by using barriers, isolators, or glove boxes, rather than remodeling their facilities to create "clean rooms." Id.

no member of the public objected to the cost of compliance with USP Chapter 797. The Board's error is therefore harmless under Minn. Stat. § 14.26, subd. (3)(d)(1).

Rulemaking Legal Standards

- 31. Under Minn. Stat. § 14.14, subd. 2, and Minn. Rule 1400.2100, a determination must be made in a rulemaking proceeding as to whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts. In support of a rule, an agency may rely on legislative facts, namely general facts concerning questions of law, policy and discretion, or it may simply rely on interpretation of a statute, or stated policy preferences. The Board prepared a Statement of Need and Reasonableness (SONAR) in support of the proposed rules. At the hearing, the Board primarily relied upon the SONAR as its affirmative presentation of need and reasonableness for the proposed amendments. The SONAR was supplemented by comments made by Board representatives at the public hearing and in written post-hearing submissions.
- 32. The question of whether a rule has been shown to be reasonable focuses on whether it has been shown to have a rational basis, or whether it is arbitrary, based upon the rulemaking record. Minnesota case law has equated an unreasonable rule with an arbitrary rule.²⁹ Arbitrary or unreasonable agency action is action without consideration and in disregard of the facts and circumstances of the case.³⁰ A rule is generally found to be reasonable if it is rationally related to the end sought to be achieved by the governing statute.³¹
- 33. The Minnesota Supreme Court has further defined an agency's burden in adopting rules by requiring it to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken." An agency is entitled to make choices between possible approaches as long as the choice made is rational. Generally, it is not the proper role of the Administrative Law Judge to determine which policy alternative presents the "best" approach since this would invade the policy-making discretion of the agency. The question is rather whether the choice made by the agency is one that a rational person could have made. 33
- 34. In addition to need and reasonableness, the Administrative Law Judge must also assess whether the rule adoption procedure was complied with, whether the rule grants undue discretion, whether the Board has statutory authority to adopt the rule, whether the rule is unconstitutional or illegal, whether the rule constitutes an undue delegation of authority to another entity, or whether the proposed language is not a rule.³⁴

²⁸ Mammenga v. Department of Human Services, 442 N.W.2d 786 (Minn. 1989); Manufactured Housing Institute v. Pettersen, 347 N.W.2d 238, 244 (Minn. 1984).

²⁹ In re *Hanson*, 275 N.W.2d 790 (Minn. 1978); *Hurley v. Chaffee*, 231 Minn. 362, 367, 43 N.W.2d 281, 284 (1950).

³⁰ Greenhill v. Bailey, 519 F.2d 5, 19 (8th Cir. 1975).

³¹ Mammenga, 442 N.W.2d at 789-90; Broen Memorial Home v. Department of Human Services, 364 N.W.2d 436, 444 (Minn. Ct. App. 1985).

³² Manufactured Housing Institute, 347 N.W.2d at 244.

³³ Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218, 233, 63 S. Ct. 589, 598 (1943).

³⁴ Minn. R. 1400.2100.

- In this matter, the Board has proposed some changes to the rule language after publication in the State Register. Thus, the Administrative Law Judge must also determine if the new language is substantially different from that which was originally proposed.35
- The standards to determine if new language is substantially different are 36. found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if "the differences are within the scope of the matter announced ... in the notice of hearing and are in character with the issues raised in that notice," the differences "are a logical outgrowth of the contents of the ... notice of hearing and the comments submitted in response to the notice," and the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question."
- In determining whether modifications make the rules substantially 37. different, the Administrative Law Judge is to consider whether "persons who will be affected by the rule should have understood that the rulemaking proceeding ... could affect their interests," whether "the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the ... notice of hearing," and whether "the effects of the rule differ from the effects of the proposed rule contained in the ... notice of hearing."36
- Any substantive language that differs from the rule as published in the State Register has been assessed to determine whether the language is substantially different. Because some of the changes are not controversial, not all of the altered language has been discussed. Any change not discussed is found to be not substantially different from the rule as published in the State Register.

Analysis of the Proposed Rules

General

This report is limited to discussion of the portions of the proposed rules that received significant comment or otherwise need to be examined. When rules are adequately supported by the SONAR or the Board's oral or written comments, a detailed discussion of the proposed rules is unnecessary. The agency has demonstrated the need for and reasonableness of all rule provisions not specifically discussed in this report by an affirmative presentation of facts. All provisions not specifically discussed are authorized by statute and there are no other problems that would prevent the adoption of the rules.

Discussion of Proposed Rules by Topic

6800.0100 - Definitions

Subpart 1c. Central Service Pharmacy. The Board proposed to define a "central service pharmacy" as "a pharmacy located in Minnesota that may provide dispensing functions, drug utilization review, packaging, labeling, or delivery of a

Minn. Stat. § 14.15, subd. 3.
 Minn. Stat. § 14.05, subd. 2.

prescription product to another pharmacy in the state for the purpose of filling a prescription."

- 41. The Board received many public comments opposing the proposed requirement that central service pharmacies be located within Minnesota. The Minnesota Pharmacists Association (MPhA), the National Association of Chain Drug Stores (NACDS), and the Minnesota Retailers Association were just a few of the groups that opposed the proposed language on the basis that it would result in unequal treatment of pharmacies in Minnesota that want to use a pharmacy located outside of the state to handle the central service functions according to their operational needs and mail order pharmacies located outside of the state that are routinely allowed to mail prescriptions into the state.³⁷ And while the proposed rules allow the Board to grant variances to out-of-state central service pharmacies, the above-mentioned associations argue that making out-of-state central service pharmacy sites contingent upon a year-to-year variance is financially risky given the substantial up-front investments that would be necessary. These associations proposed that the Board remove the language "located in Minnesota" and "in the state" from the proposed language of subpart 1c.
- 42. In its response to hearing testimony and comments dated November 22, 2006,³⁸ the Board agreed to change the proposed language as follows:

"Central service pharmacy" means a pharmacy located in Minnesota that may provide dispensing functions, drug utilization review (DUR), packaging, labeling, or delivery of a prescription product to another pharmacy in the state for the purpose of filling a prescription."

43. In addition to, and as a result of this change, the Board proposes to add a new subpart, as follows, which is based on the National Association of Boards of Pharmacy's Model Statutes and Rules:³⁹

6800.4100. Centralized Prescription Processing and Filling.

- (A) A central service pharmacy located in another state that provides any services listed in M.R. 6800.0100, subp. 1c, to a pharmacy located in this state shall be licensed as a nonresident pharmacy in accordance with Minnesota Statutes § 151.19, subd. 2.
- (B) A central service pharmacy located in this state that provides any services listed in M.R. 6800.0100, subp. 1c, to a pharmacy located in any state shall be licensed as a pharmacy in accordance with Minnesota Statutes § 151.19, subd. 1.
- (C) A pharmacy may perform or outsource Centralized Prescription Filling or Centralized Prescription Processing services provided the parties:
 - (1) have the same owner or have a written contract outlining the services to be provided and the responsibilities and accountabilities

³⁹ Ex. 30.

³⁷ Exs. 10a, 10b, and 10c; testimony of Jeff Lindoo, Tim Krause, Buzz Anderson.

³⁸ Ex. 30.

- of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
- (2) <u>share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a Prescription Drug Order;</u>
- (3) the central service pharmacy is licensed in accordance with M.R. 6800.0300; and
- (4) provide the Board with a copy of the policy and procedures manual described in clause D below at least 30 days before centralized prescription processing services begin.
- (D) The parties performing or contracting for Centralized Prescription Processing services shall maintain a policy and procedures manual and documentation that operations are occurring in a manner consistent with said manual. The manual shall be made available to the Board for review upon request and shall include, at a minimum, the following:
 - (1) a description of how the parties will comply with federal and state laws and regulations;
 - (2) the maintenance of appropriate records to identify the responsible Pharmacist(s) in the Dispensing and counseling processes;
 - (3) the maintenance of a mechanism for tracking the Prescription Drug Order during each step in the Dispensing process;
 - (4) the maintenance of a mechanism to identify on the prescription label all Pharmacies involved in Dispensing the Prescription Drug Order;
 - (5) the provision of adequate security to protect the integrity and prevent the illegal use or disclosure of Protected Health Information;
 - (6) the maintenance of a Continuous Quality Improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
- (E) A pharmacist or pharmacist intern at the pharmacy that dispenses, delivers, mails, or ships the completed prescription to the patient is responsible for certifying the completed prescription.
- (F) A pharmacist or pharmacist intern at the pharmacy that dispenses, delivers, mails, or ships the completed prescription to the patient is responsible for counseling the patient pursuant to M.R. 6800.0910.
- (G) A pharmacy utilizing a central service pharmacy to provide dispensing functions, drug utilization review (DUR), packaging, labeling,

<u>delivery of a prescription product or other services must notify its patients</u> of that fact.

- 44. The Board believes that this new subpart is a reasonable compromise. It removes the requirement that a central service pharmacy be located within Minnesota, but it makes clear that nonresident central service pharmacies have to be licensed by the Board. In addition, the Board states that this is the sort of information it would ask for if the process were being handled by variance rather than licensure.⁴⁰
- 45. A number of pharmacists and trade associations objected to item E of 6800.4100. This group has serious concerns about how the proposed rule would relate to a central fill pharmacy, where prescriptions are assembled and filled at one site and then sent to a second site where they are picked up by the patient. In their interpretation, item E indicates that in a central fill situation, a pharmacist at the second site would have to certify the accuracy of a prescription filled at the first site. This is perceived as unnecessary additional work because all of the means to certify the accuracy of a filled prescription are located at the first site where the prescription is filled, not at the second site, where the prescription is picked up by the patient. One pharmacist worried that this requirement would mean that pharmacists at the second site would have to regularly open bottles of filled prescription to check accuracy. The group believes that any attempt to move the final, critical certification process to another site would only result in a less reliable, less safe situation, with less reliable outcomes.
- 46. The Board responded that there are several different process models in place at different pharmacies and that an added accuracy check will be a benefit to patients in all of those settings. The Board responded that having a pharmacist at the facility that actually dispenses, delivers, mails or ships the finished prescription to the patient adds an important safety check to the process.⁴⁴ In addition, the Board asserted that many pharmacies that use automated systems internally or that utilize central fill facilities have developed procedures for identifying a drug that is in a filled prescription vial.
- 47. The Administrative Law Judge finds the language of 6800.0100, subp. 1c and 6800.4100 to be needed and reasonable. The Board's determination that the pharmacist who directly provides the prescription to the patient should be responsible for certification is a permissible policy decision within the Board's discretion. The Administrative Law Judge concludes that these changes do not render the remaining proposed rules substantially different from the rule as published, because centralized prescription processing and filling requirements were included in the published rule.

⁴⁰ Fy 30

⁴¹ Exs. 31, 32, 36, 37, 40, and 46.

⁴² Exs. 31 and 37.

⁴³ Exs. 36 and 40.

⁴⁴ Ex. 40.

6800.0100, subp. 4 – Long-term care pharmacy 6800.0100, subp. 4a – Assisted living facility

- 48. The Board proposes to add assisted living facilities to the definition of "long-term care pharmacy." There were no objections to this addition from the public. One trade association that represents long-term care providers suggested that the Board provide a clarifying definition of "assisted living facility."
- 49. The Board agreed to make that proposed addition and will add a definition of "assisted living facility" as follows:
 - Minn. R. 6800.0100, subp. 4a. Assisted living facility. For the purposes of this chapter, the term "assisted living facility" means a registered housing with services establishment, as defined in Minnesota Statutes, section 144D.01, subdivision 4, that provides central storage of medications for residents.
- 50. The Administrative Law Judge finds the proposed definition to be needed and reasonable, and the addition of the definition of "assisted living facility" makes the rule more accurate without rendering it substantially different from what was originally proposed.

6800.0910 - Patient Access to Pharmacist

- 51. **Subpart 2. Description of Procedure.** This subpart addresses the counseling and drug utilization review that a patient receives from a pharmacist when filling and refilling prescription orders. Currently a pharmacist's designee may offer counseling to the patient on the pharmacist's behalf, and if that offer is accepted, the pharmacist must initiate and conduct the counseling. But the proposed language requires the pharmacist to personally initiate discussion with the patient when filling each new prescription drug order. As to refilled prescriptions, "the pharmacist must counsel the patient on a refilled prescription if deemed necessary according to the pharmacist's professional judgment."
- 52. The Board proposed this language as a means of further improving and increasing the amount of counseling and DUR that is provided to patients, arguing that increased counseling and review leads to fewer medication errors and accidents. The Board believes that more patients will be counseled if the pharmacist is required to personally initiate the counseling upon filling of a new prescription, as opposed to simply offering to counsel the patient.
- 53. The MPhA, NACDS, and the Minnesota Retailers Association, among others, objected to the new mandatory counseling requirement on new prescription orders because it does not take into account the needs and choices of each patient and the judgment of the pharmacist. The NACDS argues that the rule should be tailored to the patient, the prescribed drug, and the patient's circumstances, and must allow for the pharmacists' professional judgment. The NACDS asserts that the requirement is

⁴⁵ Ex. 10h.

⁴⁶ Ex. 10b.

arbitrary and fails to allow pharmacists to determine which prescriptions require counseling.

54. In addition, these same organizations also argue that the proposed rule does not provide equal treatment of retail pharmacies versus mail order pharmacies, the latter of which are permitted to dispense prescriptions by mail and provide written information. The organizations suggest that this will have a disparate economic impact on retail pharmacies versus mail order pharmacies. Accordingly, the NACDS proposed additional language in subpart 2, item A, as follows:

Upon receipt of a new prescription or a new prescription drug order for a prescription drug that the patient has not previously had filled at the pharmacy, following a review of the patient's record, and upon acceptance of an order to consult, a pharmacist shall pursuant to the pharmacist's professional judgment personally initiate discussion of matters which in the professional judgment of the pharmacist will enhance or optimize drug therapy with each patient or the agent or caregiver of the patient. The discussion shall be in person, whenever practicable applicable, or according to the means determined by the pharmacist's professional judgment and may be supplemented with or provided in person, by telephone, or by written material, and shall include appropriate elements of patient counseling. These elements may include the following: 48

- 55. Several commenters objected to the withdrawal of the language permitting a pharmacist's designee from providing the offer to counsel. One individual asked that the language be left in the rule and made stronger so that patients understand that the pharmacist must counsel them upon filling new prescriptions.⁴⁹
- 56. The Board responded to these comments twice, once in its Response to Comments Received During the October 2-November 1, 2006 Comment Period and once in its post-hearing response dated November 22, 2006. It reiterated its position about the importance of mandatory counseling on new prescriptions. The Board declined to change the proposed language, stating that "[a]s long as language exists that makes it acceptable to merely 'offer' to counsel, it is likely that an inadequate amount of counseling will take place. The rule will have no 'teeth' if counseling on new prescriptions is not mandatory." 50
- 57. Furthermore, the Board addressed the concerns about any potential disparate economic treatment as the proposed rule relates to retail pharmacies versus mail order pharmacies. The Board argues that the distinction is reasonable because of the significant differences between the populations served by retail pharmacies and those served by mail order services. Typically, institutional practice settings, such as hospitals and nursing homes, use mail order pharmacies. The Board asserts that in an

⁴⁷ Exs. 10a, 10b, and 10c.

⁴⁸ Ex. 10b, p. 3.

⁴⁹ Ex. 30.

⁵⁰ Ex. 30.

⁵¹ Ex. 12.

institutional setting, a licensed healthcare professional, such as a nurse, will administer the drug and will have the direct opportunity to provide counseling before the patient This is typically not the situation for patients who pick up their prescriptions from retail pharmacies, so the Board feels strongly that the counseling on new prescriptions should be mandatory.

58. The Board has established that the proposed rule is needed and reasonable. This is a choice that is legitimately within the agency's policy-making discretion.

6800.1050 - Required Reference Books and Minimum Equipment for Pharmacies

- **Subpart 1. Reference books.** The revision to this rule language updates the requirements for the types of reference books that pharmacies must have on hand. Specifically, the Board proposes to allow many references to be in either hard copy or electronic form; to require that each pharmacy have a current copy of the Drug Enforcement Agency regulations, Code of Federal Regulations, title 21, parts 1300 to 1316 on hand; to require that at least one dosage and toxicology reference be in hard copy form and that the reference be appropriate to the majority of the patient base of the pharmacy; and to require specialty pharmacies serving a unique population to have a current general reference appropriate to the patient base served. 52
- Both the NACDS and the Minnesota Retailers Association objected to the requirement that at least one dosage and toxicology reference be in hard copy form.⁵³ The associations argue that the pharmacies of today are almost entirely computerized and that they routinely use electronic references. Further, they state that electronic references are updated continually and able to be printed if necessary.
- The Board defended its proposed revisions stating that a frequently-61. consulted reference should be in hard copy in the event that there is a computer or website error which renders the electronic form of the reference unavailable. 54
- The Administrative Law Judge concludes that the Board 62. demonstrated that the reference book requirements of subpart 1 are needed and reasonable.
- Subpart 2. Equipment. The Board made a number of revisions to this 63. subpart. The only change that generated any negative public comment was the requirement that pharmacies maintain a daily log of refrigerator temperatures. The Board argues that it is aware of pharmacies that do not monitor their storage refrigerator temperatures and wishes to prevent improperly stored drugs from being distributed to patients.55
- The NACDS and the Minnesota Retailers Association objected to this requirement as an "operational burden." Both associations suggested alternative

⁵⁴ Ex. 12.

⁵² SONAR at 5.

⁵³ Exs. 10b and 10c.

⁵⁵ SONAR at 6.

language that would require pharmacists to report temperature problems to the supervising pharmacist.⁵⁶

- 65. The Board was not convinced by the suggested changes, asserting that the two associations did not offer an explanation for why they believed this requirement would be burdensome.⁵⁷ The Board argues further that its proposed language is consistent with the standards adopted by other regulatory bodies and that many pharmacies in Minnesota already comply with the Board's proposed rule change.⁵⁸
- 66. The Administrative Law Judge concludes that the Board has demonstrated that the storage requirements of subpart 2 are needed and reasonable.

6800.1300 - Reciprocity

- 67. **Subpart 4. NAPLEX examination.** The Board proposes to require that applicants who have not engaged in practice as a licensed pharmacist for the two years immediately preceding the filing of their application for reciprocal licensure take the NAPLEX examination rather than a practical examination.⁵⁹ The Board no longer requires applicants for licensure to complete and pass a practical examination, so it was necessary to amend the language of subpart 4.
- 68. The NACDS and the Minnesota Retailers Association objected to this subpart on the grounds that the language about not having practiced pharmacology for two years is vague and arbitrary and that the Board has too much discretion in determining who will have to take the NAPLEX examination.⁶⁰
- 69. The Board points out in its response that the requirements of subpart 4 have been in effect for many years and have never been questioned as being vague or arbitrary. The Board relies on the definition of "practiced pharmacy" set forth in Minn. Stat. § 151.01, subd. 27 when making determinations about what constitutes the practice of pharmacy. 61
- 70. The language to which the associations object is not a part of this rulemaking. The Administrative Law Judge concludes that the Board has demonstrated that the amendment to subpart 4 is needed and reasonable.

6800.1500 - Continuing Pharmacy Education

- 71. **Subpart 2. Minimum hours required; reporting.** The Board proposed two additions to the language of subpart 2, the second of which requires payment of \$100 from pharmacists who request an extension on the reporting of their continuing education requirements.
- 72. The Board did not receive any comments on this particular language, but in its post-hearing comments dated November 22, 2006, the Board acknowledged that it does not have the statutory authority to require payment of a fee. Accordingly, the

⁵⁹ SONAR at 6-7.

⁵⁶ Exs. 10b and 10c.

⁵⁷ Exs. 12 and 30.

⁵⁸ Ex. 12.

⁶⁰ Exs. 10b and 10c.

⁶¹ Ex. 12.

Board is withdrawing the proposed language regarding the \$100 fee.⁶² The Board has established that the rule language, without the \$100 fee, is needed and reasonable and within the Board's statutory authority.

6800.2350 - Pharmaceutical Waste

- 73. The Board proposes the following language for this new rule part: "Hazardous pharmaceutical waste disposal shall comply with chapter 7045 as enforced by the Pollution Control Agency (MPCA) and other authorized state agencies."
- 74. The Board recognizes that disposal of many prescription drugs is considered to be disposal of hazardous waste by either federal or state agencies. Also, many chemicals used by pharmacists during the extemporaneous compounding of drug products are toxic, flammable or corrosive. The Board argues that improper disposal of these drugs and chemicals poses a risk of harm to the public. The Board engaged in discussions with the MPCA and learned that the MPCA has started to actively enforce its rules concerning disposal by healthcare facilities of hazardous wastes. ⁶³ Consequently, the Board deemed it necessary to require that disposal of hazardous pharmaceutical waste be in compliance with the Minnesota Hazardous Waste Rules, Chapter 7045.
- 75. A number of public commenters opposed the adoption of this rule part, including the MPhA, the NACDS, the Minnesota Retailers Association, and the Mayo Clinic.⁶⁴ These associations assert that the inclusion of this language is redundant, vague, and unnecessary. The Mayo Clinic argues that it is extremely difficult to extract exactly which parts of Chapter 7045 are pertinent to pharmacies. All four associations suggested that the Board, in conjunction with the MPCA, put together guidelines to help pharmacies comply with the chapter. At least three of the groups suggested that the proposed language be stricken altogether.⁶⁵
- 76. In its post-hearing comments, the Board reiterated its commitment to including this language, emphasizing that pharmacies already have to dispose of pharmaceutical waste in accordance with the relevant pollution control statutes and rules. By adopting this new language, the Board is not imposing any new requirements on pharmacies but is helping to educate pharmacists about the issue and about how the MPCA will react to pharmacies that do not comply with the rules. Furthermore, the rule language gives the Board the power to initiate disciplinary action for violation of the rule. Furthermore, the rule.
- 77. The Administrative Law Judge concludes that the Board has demonstrated that this proposed rule part is needed and reasonable. The rule does not create a new obligation for pharmacies; it simply references existing rules of the MPCA. The suggestion that the Board and the MPCA put together guidelines to assist

63 SONAR at 8.

⁶² Ex. 30.

⁶⁴ Exs. 10a, 10b, 10c, and 10n.

⁶⁵ Exs. 10a, 10b, and 10c.

⁶⁶ Ex. 30.

⁶⁷ Ex. 12.

pharmacies with compliance is well-founded, particularly if the Board intends to initiate disciplinary action for violations of MPCA rules.

6800.2700 - Return of Drugs and Devices.

- **Subpart 2, item B.** The Board proposed several changes to this rule part, one of which received numerous comments from the public. Subpart 2 is a list of the requirements, A-F, that must be met before drugs from nursing homes may be returned to the dispensing pharmacy and redispensed. Item B requires that "the facility has 24hour, on-site licensed nursing coverage seven days a week." The Board proposed this language because it would ensure that licensed health professionals would either have control of the dispensed drugs or be able to monitor them 24 hours per day, seven days per week. In the Board's opinion, not having licensed nursing coverage increases the risk that drugs might be tampered with or that they will not be stored properly.⁶⁸ The rule as currently written does not allow pharmacies to accept returns, for reuse, from county correctional facilities or assisted-living facilities.
- Item B received significant public opposition from individuals representing county boards, jails, sheriff's departments and public health agencies. The counties suggest that the adoption of the proposed language will result in significant costs to county taxpayers. 69 The storage of medications in jails is governed by Minnesota Rules, Chapter 2911, which requires correctional facilities to store prescription drugs in original containers with original labeling. Those rules also require that the facility have a procedure in place for "maximum security storage of and accountability for controlled substances." In addition, medications are supposed to be stored in an area that is locked when not in use by authorized staff. Inmates are not permitted access to the locked area and only "health-trained staff" are allowed to have access to the locked area.70
- 80. Several counties indicated that the Board's past practice has been to grant variances to pharmacies allowing them to accept and redispense medications returned from county correctional facilities.71 Similar variances have allowed pharmacies to accept returns for reuse from assisted-living facilities. The proposed rule language indicates that the Board is no longer in favor of granting such variances.
- The Board defended the proposed language and responded that its primary concern is the health and safety of the public. But it did concede that the proposed language, if adopted, would have a fiscal impact on county jails which have been returning medications to pharmacies on the basis of variances granted by the Board. The Board challenged the magnitude of the cost impact on county jails by analyzing the expenditures of two counties that reported the specific dollar amounts of their returned medications. The Board pointed out that the returned medications represent only between 0.025% to 0.05% of those counties' total expenditures.

⁷² Ex. 12.

⁶⁸ SONAR at 10.

⁶⁹ Testimony of representatives of the Minnesota Sheriffs Association, the Association of Minnesota Counties, and the Minnesota Health and Housing Alliance. See also Exs. 10z, 27, and 28. ⁷⁰ Minn. R. 2911.6400.

⁷¹ Ex. 28.

- 82. The Board is entitled to make this policy choice as long as it is rationally related to public health and safety, which it is. The Administrative Law Judge concludes that the Board has demonstrated that this proposed rule part is needed and reasonable.
- 83. **Subpart 2, item F.** Item F of subpart 2 also generated negative public comment and reads as follows: "the pharmacy ensures that patients who may receive returned drugs, are notified that the pharmacy accepts and redispenses drugs returned from approved facilities." The Board added this language because it believes that patients have a right to make an informed decision as to whether or not they want to accept a drug that has been previously dispensed by the pharmacy.⁷³
- 84. The trade associations and individuals who objected to this item are concerned that this disclosure requirement would cause confusion among patients and may lead to patients refusing to receive drugs that have been returned and redispensed from approved facilities. If the Board has determined that the practice of accepting returned medications from approved facilities and redispensing them is a safe practice, then there should be no reason for such a disclosure. If the practice is not safe, then the Board should discontinue it altogether.
- 85. Care Providers of Minnesota expressed concern that giving the disclosure will cause their nursing home patients to ask for their medications from different pharmacies, which will put nursing facilities in an "untenable position." Care Providers also worried that it will be the nursing facilities' obligation to provide the disclosure, which will result in increased paperwork and workload for staff who already have too much to accomplish.
- 86. Governor Pawlenty and his staff also object to item F on the grounds that the notification requirement would reduce the return and redispensing of safe and effective drugs, resulting in increased waste in the healthcare system.⁷⁶
- 87. As a result of all of these comments and concerns, the Board has agreed to withdraw the proposed language of item F.
- 88. **Subpart 2 generally.** As discussed above, subpart 2 addresses the return and redispensation of drugs from nursing homes. The Minnesota Health & Housing Alliance (MHHA) objected to the fact that assisted living facilities were not included in this subpart. MHHA argued that the number of older adults currently residing in senior housing settings with services far exceeds the number residing in nursing homes, and that assisted living facilities are expected to serve an increasing number of frail seniors as the number of nursing home beds continues to decline. MHHA goes on to argue that assisted living providers are bound by Minnesota's home care rules dealing with medication administration, storage, and disposal, as well as the Nurse Practice Act, when dealing with residents' medications. Currently, many pharmacies accept returned drugs from assisted living facilities under a variance or

⁷³ SONAR at 10.

⁷⁴ Exs. 10a, 10h, 10j, and many others.

⁷⁵ Ex. 10h.

⁷⁶ Ex. 12.

⁷⁷ Ex. 10j.

waiver process. But MHHA asserts that the Board has recently been unresponsive to pharmacies' requests for these types of variances or waivers.⁷⁸

- Another argument set forth by MHHA is that the following language is 89. ambiguous: "Drugs from nursing homes may be returned to the dispensing pharmacy and redispensed if: . . ." MHHA suggests that adding the word "redispensed" after the conjunction "and" arguably applies all of the items after the colon to both terms joined by the conjunction (returned and redispensed), particularly because four of the items apply to the term "returned" in the current language.
- Based upon these reasons, MHHA proposed amended language, which the Board accepted, in substantially the same form, as follows:
 - Subp. 2. Drugs from nursing homes and assisted living facilities. Drugs from nursing homes and assisted living facilities may be returned to the dispensing pharmacy. The returned drugs may be redispensed if:
- 91. MHHA also recommended that assisted living facilities meeting the requirements of Minnesota Statutes, chapter 144G be exempt from item B (see discussion above). The Board, however, declined to accept this language and intends to hold assisted living facilities to the same standards by which nursing homes must abide.80
- The Administrative Law Judge finds the Board's proposed amended language to be needed and reasonable, and the change makes the rule more inclusive and less ambiguous without rendering it substantially different from what was originally proposed.

6800.3100 - Compounding and Dispensing

- Subpart 1. Duties. This subpart governs the practice of compounding and dispensing prescriptions and limits the performance of those duties to pharmacists. practitioners, or pharmacist-interns under the immediate and personal supervision of a pharmacist.
- Daniel Maddox of the Minnesota Allergy Society questioned the Board at the hearing about whether this rule applies to allergen immuno-therapy that is performed in an allergist's office. He requested that the Board add language to subpart 1 that specifically excludes allergists.
- The Board's executive director clarified at the hearing that the rule is not intended to regulate therapies performed in an allergist's office. Furthermore, the Board stated that it has no authority to regulate medical practice and that under Minn. Stat. § 151.37, prescribers of medication are permitted to dispense medication.
- Subpart 3b. Notice required. The Board proposes the following new language: "A pharmacy utilizing services from a central service pharmacy must notify its patients that the pharmacy outsources prescription filling to another pharmacy." The

⁷⁸ Ex. 10j. ⁷⁹ Ex. 10j.

⁸⁰ Ex. 12.

Board proposed this language because it believes that patients have a right to make an informed decision about where their prescriptions are filled.⁸¹

- 97. The Minnesota Retailers Association, the NACDS, and the Mayo Clinic objected to this language.⁸² These groups argued that use of the word "outsource" implies that the pharmacy is obtaining its prescriptions from an outside company. They suggest that the notice should be required only if the central fill pharmacy is not owned by the distributing pharmacy.
- 98. The Minnesota Retailers Association and the NACDS again put forth the argument that this notice requirements will result in unequal treatment of pharmacies in Minnesota that may want to use a central service pharmacy.⁸³
- 99. Based on the comments put forth regarding the word "outsource," the Board proposed to amend the proposed language to read as follows: "A pharmacy utilizing a central service pharmacy to provide dispensing functions, drug utilization review (DUR), packaging, labeling, delivery of a prescription product or other services must notify its patients of that fact."
- 100. As for the unequal treatment argument, the Board stood by its proposed language stating that it cannot guarantee equal treatment of nonresident pharmacies, but that the rules will ensure that all pharmacies located in Minnesota are subject to the laws and rules of this state.
- 101. The Administrative Law Judge concludes that the Board has established that the proposed amendments are not substantially different from what was originally proposed. The proposed rules and the changes thereto are needed and reasonable.

6800.3200 - Prepackaging and Labeling

- 102. **Subpart 2. Labeling.** This subpart governs the information that must appear on the label of a prepackaged container. Prepackaging is a repackaging of medications from the manufacturer's container into another package. Prepackaging is generally done in bulk quantities and stored to be dispensed at a later date to the patient. The Board proposes to add item F, which requires: "after July 1, 2008, a physical description, including any identification code that may appear on tablets and capsules." In the Board's judgment, this additional labeling requirement is a means by which a patient or caregiver can compare the drug dispensed against the description on the label to detect any error before taking the drug. Board is a repackaging of medication and the label to detect any error before taking the drug.
- 103. The MPhA objected to this new requirement. The association stated that they have been contacted by members who provide service to institutional facilities who are concerned about how this requirement pertains to unit dose packaging. The MPhA argues that the language is vague as to the definition of a "prepackaged container," and seeks clarification as to whether unit dose packages are included in the meaning of

⁸² Exs. 10b, 10c, and 10n.

⁸¹ SONAR at 12.

⁸³ See discussion under Minn. R. 6800.0100, subp. 1c. Exs. 10b and 10c.

⁸⁴ Ex. 23.

⁸⁵ SONAR at 13.

"prepackaged container." The association expressed concern that it would be physically impossible to label individually some unit dose packages.

- 104. Jeff Lindoo of Thrifty White Pharmacy objected to this requirement as redundant in relation to the proposed prescription labeling language of Minn. R. 6800.3400, subp. 1, discussed below. Mr. Lindoo suggested that two new labeling requirements are unnecessary and duplicative. He supports the prescription labeling requirement under Minn. R. 6800.3400, but not the proposed language of Minn. R. 6800.3200, subp. 2. Accordingly, Mr. Lindoo proposed that the Board amend the proposed language to exclude or exempt unit dose packaging in which the appearance of the product is visible in the package.87
- 105. In its first response to public comments, the Board clarified that subpart 2, item F does indeed apply to unit dose packaging. 88 Subsequently, based on the testimony at the hearing, the Board has proposed additional language to subparts 1 and 2 of this rule part. To address the concern that it is physically impossible to label some individual unit dose packages because of their small size, the Board proposes to add to subpart 1 a reference to the USP general chapter 1146, entitled "Packaging Practice: Repackaging a Single Solid Oral Drug Product in a Unit Dose Container."89 This additional reference would require that either (1) the unit doses are dispensed in a larger container that does have a label that contains a physical description of the drug, or (2) the unit doses are dispensed in a less than 72-hour supply.
 - 106. Similarly, the Board proposes the following change to subpart 2, item F:

After July 1, 2008, a physical description, including any identification code that may appear on tablets and capsules or a barcode based on the National Drug Code (NDC). Such a description does not need to be placed on individual unit-doses, provided that the pharmacy dispenses the unit-doses in outer packaging that does contain a physical description of the drug or the pharmacy dispenses less than a 72 hour supply of the unitdoses.

107. The Administrative Law Judge finds the proposed amended language to be needed and reasonable. The additional reference to and explanation of USP chapter 1146 gives pharmacies added flexibility in complying with the labeling requirements of the rules without rendering it substantially different from what was originally proposed.

6800.3400 - Prescription Labeling

108. Subpart 1. Requirements applicable to all drugs. Subpart 1 is a list of requirements that must appear on the label of a prescription given to a patient, other than an inpatient of a hospital. The Board proposes to add two labeling requirements, items J and K, to subpart 1 as follows:

⁸⁶ Ex. 10a. ⁸⁷ Ex. 23.

⁸⁸ Ex. 12.

⁸⁹ Ex. 30.

J. prescriptions filled as part of a central service operation shall bear a unique identifier to indicate that the prescription was filled at a central service pharmacy; and

K. after July 1, 2008, any dispensed prescription medication shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.

The purpose of these two items, according to the Board, is to decrease the number of dispensing errors and keep patients informed about the physical characteristics of their medication and where their prescription was filled.⁹⁰

109. As to item J, the Mayo Clinic Pharmacy put forth the same argument as discussed under Minn. R. 6800.3100, subp. 3b above. Similarly, the public objection to item K that arose under the discussion of Minn. R. 6800.3200, subp. 2, surfaced again in this section. The Mayo Clinic expressed concern that label space is already limited and crowded:

If this amount of information is added to the label, either something else on the label will have to be downsized, adding to the difficulty of reading prescription labels to begin with, or a bigger label; therefore, bigger bottles will be needed. Bigger bottles only facilitate the practice of patients transferring their medications to smaller, more manageable containers. This introduces a whole new set of safety issues. . . . Information on the label should be reserved for that which the patient needs to see each time they go to take that medication. Including tablet description on the patient information leaflet or receipt should be considered acceptable to fulfill this requirement. ⁹²

- 110. The Board respectfully disagreed with the arguments presented regarding items J and K for the reasons discussed above under Minn. R. 6800.3100, subp. 3b and 6800.3200, subp. 2. Specifically, the Board cites to three other states that have promulgated regulations requiring that prescription medication container labels include the color, shape and any identification code appearing on the tablets or capsules. The Board also mentions a robotic dispensing system, ScriptPro, that creates labels that include a line drawing and physical description of the drug.⁹³
- 111. The Administrative Law Judge finds the proposed language to be needed and reasonable. This is a policy choice the Board is entitled to make in the interests of public health and safety.
- 112. **Subpart 4. Veterinary prescription drug label.** The proposed language of subpart 4 regulates the type of information that must be included on a veterinary prescription drug label. The subpart contains ten different pieces of information, one of which is "the name and address of the prescribing veterinarian." The Board currently

⁹⁰ SONAR at 14.

⁹¹ Ex. 10n.

Ex. 10n. See also Testimony of Tim Krause, Omnicare Long-Term Care Pharmacy and Lisa Gersema,
 Minnesota Society of Health-System Pharmacists.
 Ex. 12.

has no rule concerning the labeling of veterinary prescriptions. Until recently, most such drugs were dispensed directly by the veterinarian to the owner of the animal for which the drug was prescribed. There are now pharmacies specializing in dispensing veterinary drugs to animal owners, however, and the Board wishes to impose labeling requirements. These ten items are based on the labeling requirements for veterinarians and their authorized agents contained in Minn. Stat. § 156.18, subd. 2, a statute enforced by the Minnesota Board of Veterinary Medicine.

- 113. The Mayo Clinic Pharmacy objected to the requirement to include the name and address of the prescribing veterinarian on the label. The Mayo Clinic argues that because the pharmacy is filling the prescription, and not the veterinarian, it makes no sense to include the address of the veterinarian when such information is not even required on human prescriptions. In order to comply with this requirement, most pharmacies would have to include the address of all prescribers on their labels since trying to do so only for veterinarians would be difficult. This again leads to problems with limited space available on the labels. 96
- 114. The Board, in its initial response to comments, agreed to remove the address requirement from the proposed rules.⁹⁷ Subsequently, the Board overlooked that it had agreed to remove item A, and in its comments dated November 22, 2006, it proposed different language to address the concerns identified at the hearing:

Subp. 4. Veterinary prescription drug label. A veterinary prescription drug label must include:

A. the name and address of the prescribing veterinarian; except that the address of the prescribing veterinarian is not required if the prescription is for a companion animal. For the purposes of this subpart, a companion animal is a member of a species that is normally kept by humans for companionship and enjoyment, rather than normally being raised for consumption as food.

The Board's reasoning for this proposal is that a typical community/retail pharmacy does not dispense prescriptions for food-producing animals. Consequently, the address requirement would almost exclusively affect the specialty pharmacies that provide prescriptions for farm animals.⁹⁸

115. The Administrative Law Judge finds that the Board has not demonstrated why this subsequently proposed language is needed or reasonable. Nowhere in the SONAR or other comments does the Board point to any reason for requiring a veterinarian's address on the label of medications intended for animals being raised for the consumption of food, as opposed to medications intended for "companion animals." Furthermore, the newly proposed language defining a "companion animal" is impermissibly vague. Finally, it appears to be virtually impossible for a pharmacist presented with such a prescription written by a veterinarian to determine whether it is

⁹⁴ SONAR at 15.

⁹⁵ Ex. 10n.

⁹⁶ See also Testimony of Tracy Berg and Gerald Christenson, Mayo Clinic.

⁹⁷ Ex. 12.

⁹⁸ Ex. 30.

intended for a "companion animal" as opposed to one being raised for food consumption. These are defects in the newly proposed rule language, which can be corrected by removing item A in its entirety, as initially proposed by the Board in its first response to public comments.

6800.3450 – Labeling of Outpatient Intravenous Admixture Drugs

- 116. **Subpart 1. Requirements applicable to intravenous admixture drugs.** The Board wishes to correct an oversight in the proposed language of subpart 1, item E. 99 Tim Krause of Omnicare Long-Term Care Pharmacy and Christine Koentopp of Children's Hospital both testified at the hearing regarding this proposed language, and the Board now agrees to change the proposed language as follows:
 - E. sequential number of unit, if appropriate administration times, administration frequency or both; . . ."
- 117. The Board merely seeks to correct an oversight that was discussed accurately in the SONAR but not conveyed in the rule draft. The Administrative Law Judge finds that the proposed language is needed and reasonable, and it does not represent a substantial change from the rule as originally proposed.

6800.3950 - Electronic Data Processing; Computer Usage

- 118. **Subpart 4. New prescriptions.** Currently, this rule part requires pharmacists to verify, upon the first refill, that information has been correctly entered into the electronic data processing system by comparing the data entered into the computer with the original hard copy of the prescription. Alternatively, a pharmacy is allowed to develop a quality assurance plan that provides safeguards against errors being made and perpetuated due to inaccurate prescription data being entered into the pharmacy's computer.
- 119. Since the adoption of this rule, nearly all pharmacies have chosen to develop a quality assurance plan that includes the comparison of the original hard copy prescription, or an image thereof, to the information entered into the computer. This process is generally completed between two to 72 hours after the prescription has been initially certified. Accordingly, the Board has proposed the following new language for subpart 4 and renamed the subpart "New prescriptions" instead of "Prescription refills."
 - A. A pharmacy must develop and implement a written quality assurance plan that includes the pharmacist comparing the original written prescription or an image of the original written prescription, to the information entered into the computer, and documenting the completion and accuracy of this comparison with the date and initials of the pharmacist completing the task. This process must not occur prior to two hours after the prescription has been initially certified, unless it is completed by a second individual pharmacist as soon as possible after

¹⁰⁰ SONAR at 16.

⁹⁹ Ex. 30.

¹⁰¹ SONAR at 16.

- the initial certification has occurred. The process must be completed within 72 hours.
- B. As an alternative to the requirements of item A, hospitals providing inpatient pharmacy services may elect instead to develop a plan to provide safeguards against errors being made and perpetuated due to inaccurate prescription data being entered into the pharmacy's computer. This written quality assurance plan shall be made available to the board surveyors upon request.
- 120. The Board has proposed this language because waiting to make the quality assurance check until the first refill can mean that the patient is taking a drug incorrectly for days or weeks before the error is caught. In addition, the Board reasons that most pharmacies have already adopted a quality assurance plan that is substantially similar to this. The Board proposed an alternative for hospitals because they typically employ a variety of prescription order entry systems where nurses and pharmacists perform accuracy checks on prescriptions prior to dispensing them to patients. The Board wishes to allow hospital pharmacies additional flexibility in their quality assurance policies so that they can be tailored to the specific data entry and drug administration systems used in the facility.
- 121. A number of public comments objected to this proposed rule change for several different reasons. The Mayo Clinic argued that this requirement would cause quality pharmacies that currently double check all prescriptions before they go to the patient to force a pharmacist working alone to either dispense the product after the first check if the patient wanted it within two hours, or force the pharmacist to do a triple check, consisting of a second check right away to dispense and then a third check two hours later. The Mayo Clinic asserted that, due to a shortage of pharmacists and an increased demand for more pharmacist/patient interaction, some pharmacies will dispense after the first check only, thereby decreasing the quality of pharmacy services provided to comply with this rule change. The Mayo Clinic asserted to the quality of pharmacy services provided to comply with this rule change.
- 122. Additionally, the NACDS expressed concern that this proposed rule change is rigid, arbitrary, and lacking reasonable flexibility so that pharmacies are unable to develop a process that works within their operational model and work flow for the comparison process. They further argue that this regulation does not treat all pharmacies similarly because it allows hospitals to have an alternative process. 106
- 123. Finally, Omnicare Long-Term Care Pharmacy opposed the proposed rule because it requires more than it appears to require. In Omnicare's view, a pharmacy technician could perform the comparison task because it does not require professional judgment. Omnicare objects to the rule on the basis that it allows the quality assurance check to be made by the same pharmacist, thereby ignoring that the

¹⁰² SONAR at 17.

¹⁰³ Ex. 10n

Ex. 1011. Ex. 1011. Ex. 1011. Ex. 1011.

¹⁰⁵ Ex. 10b.

¹⁰⁶ Testimony of Jeff Lindoo.

¹⁰⁷ Ex. 43; testimony of Tim Krause.

breakdown in clinical review quality may be due to that pharmacist's lack of knowledge; allows a new prescription, with its possible clinical error, to be released and used for three days or more; diminishes ultimate accountability for serious clinical errors that are not caught by the second clinical review; and acknowledges retail and hospital pharmacies while ignoring long-term care pharmacies. Omnicare's position is that the second check need not be a clinical review and should only be an accuracy check. Such a check could be performed by a pharmacy technician and is consistent with the Board's long-standing position on use of ancillary personnel.

- 124. The Board's response to these comments was a reiteration of the statements made in the SONAR, and it declined to make changes to this proposed rule part.
- 125. The Administrative Law Judge finds that the proposed changes are needed and reasonable. Much of the proposed language is substantially similar to the current rule and does not represent a significant change in what is required of retail and hospital pharmacies. The Board may wish to consider some of the concerns expressed by Omnicare prior to adopting the proposed rules. The Board may also wish to clarify how long-term care pharmacies fit into the requirements of this rule part.

6800.7400 - Hospital Pharmacist-in-Charge

- 126. **Subpart 5. Span of control.** The pharmacist-in-charge is responsible for inspection of all areas of the hospital where drugs are stored. The purpose of the inspection is to verify proper drug storage, document distribution and administration of controlled substances, ensure the absence of outdated drugs, and maintain the integrity of the required emergency drug supply. The current rule mandates that an inspection takes place at least once every two months. The Board seeks to require inspection on a monthly, rather than bi-monthly, basis. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) does not specify the required frequency of these inspections, but only mandates periodic inspection to ensure proper storage of medication. Because the JCAHO does note that most organizations conduct these inspections at least monthly, the Board wishes to amend the rule to reflect the industry standard of practice. The supplementation of the second standard of practice.
- 127. Several organizations objected to this new proposed requirement. The Minnesota Society of Health-System Pharmacists (MSHP) maintained that monthly inspections are not the standard of practice in Minnesota. They argued that because of the current rule language, the vast majority of unit inspections are done on a bi-monthly basis. MSHP asserted that it was not aware of a Minnesota facility that has undergone a JCAHO visit and been cited for failure to perform monthly unit inspections.¹¹¹
- 128. MSHP, the Mayo Clinic Pharmacy, and Allina Hospitals and Clinics all argued that changing the frequency of unit inspections is not likely to alter the

¹⁰⁸ Ex. 43. Tim Vordenbaumen of Omnicare wrote that the second pharmacist verification is unnecessary given Omnicare's unique workflow and process as a long-term care pharmacy. Ex. 44.

¹⁰⁹ SONAR at 19.

¹¹⁰ SONAR at 19.

¹¹¹ Exs. 24 and 45.

effectiveness of the inspection process and will likely result in additional cost and personnel burdens for pharmacies with no identifiable patient value. 112

129. The Administrative Law Judge finds that the Board has demonstrated that the proposed rule is needed and reasonable. The Board is entitled to encourage Minnesota pharmacies to meet the higher standard of practice (monthly inspections) reflected in the JCAHO note. This again is a policy choice the Board has the discretion to make in the interests of public health and safety.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

- 1. The Board of Pharmacy gave proper notice of the hearing in this matter.
- 2. The Board has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule, with the exceptions noted in Findings 24 and 30, which were found to be harmless error.
- 3. The Board has demonstrated its statutory authority to adopt the proposed rules and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii).
- 4. With the exception noted in Finding 115, the Board has documented the need for and reasonableness of its proposed rules with an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2, and 14.50 (iii).
- 5. The modifications to the proposed rules that were offered by the Board after publication in the State Register do not make the rules substantially different from the proposed rule within the meaning of Minn. Stat. §§ 14.05, subd. 2, and 14.15, subd. 3.
- 6. The Administrative Law Judge has suggested action to correct the defect cited in Conclusion 4, as noted at Finding 115.
- 7. Due to Conclusion 4, this Report has been referred to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.
- 8. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are hereby adopted as such.
- 9. A finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Board from further modification of the proposed rules based upon an examination of the public comments, provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

 $^{^{\}rm 112}$ Exs. 22, 24, 26, and 45; testimony of Karen Bergrud.

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted except as otherwise noted above.

Dated this 11th day of January 2007.

/s/ Kathleen D. Sheehy
KATHLEEN D. SHEEHY
Administrative Law Judge

NOTICE

The Board must wait at least five working days before taking any final action on the rules. During that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minnesota Rules, part 1400.2100, and Minnesota Statutes, section 14.15, subdivisions 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the Commissioner of actions that will correct the defects. If the Board elects to make any changes to the rule, it must resubmit the rule to the Chief Administrative Law Judge for a review of those changes before adopting the rule.

However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the Board may either follow the Chief Administrative Law Judge's suggested actions to cure the defects or, if the Board does not elect to follow the suggested actions, it must submit the proposed rule to the Legislative Coordinating Commission, and the House of Representatives and Senate Policy Committees with primary jurisdiction over state governmental operations for the advice of the Commission and Committees.

When the rule is filed with the Secretary of State by the Office of Administrative Hearings, the Board must give notice to all persons who requested that they be informed of the filing.